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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/534,742 | 06/01/2005 | Corrado Fogher | GRT/4161-12 | 1064 |

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| EXAMINER | |
|---|---|
| WORLEY, CATHY KINGDON | |
| ART UNIT | PAPER NUMBER |
| 1638 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/534,742 | FOGHER, CORRADO | |
| | Examiner | Art Unit | |
| | CATHY K. WORLEY | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 (in part), drawn to a non allergenic, rising food flour derived from the seed of a plant expressing in said seed a gene coding for the transglutaminase enzyme and one or more genes coding for wheat storage proteins comprising SEQ ID NO:11, wherein said plant is a cereal or a leguminosa provided that said plant is not wheat, and wherein the wheat storage proteins are not modified by mutagenesis.

Groups II-X, claim(s) 1, 2 and 3 (in part), drawn to a non allergenic, rising food flour derived from the seed of a plant expressing in said seed a gene coding for the transglutaminase enzyme and one or more genes coding for wheat storage proteins

comprising SEQ ID NO:11, wherein said plant is a cereal or a leguminosa provided that said plant is not wheat, and wherein the wheat storage proteins are modified by mutagenesis to eliminate allergenic amino acid sequences for food allergies to gluten, wherein the sequence to be modified is specified; and wherein the sequence to be modified for groups II-X is SEQ ID NO: 36-44, respectively.

GROUPS I-X ARE LINKED BY CLAIM 1 AND CLAIM 4

Group XI, claim(s) 5 and 9 (in part), drawn to a transgenic plant and seed expressing a gene coding for the transglutaminase enzyme and one or more genes coding for wheat storage proteins comprising SEQ ID NO:11, wherein said plant is a cereal or a leguminosa provided that said plant is not wheat, and wherein the wheat storage proteins are not modified by mutagenesis.

Groups XII-XX, claim(s) 5-7 and 9 (in part), drawn to a transgenic plant expressing a gene coding for the transglutaminase enzyme and one or more genes coding for wheat storage proteins comprising SEQ ID NO:11, wherein said plant is a cereal or a leguminosa provided that said plant is not wheat, and wherein the wheat storage proteins are modified by mutagenesis to eliminate allergenic amino acid sequences for food allergies to gluten, wherein the sequence to be modified is specified; and

wherein the sequence to be modified for groups XII-XX is SEQ ID NO: 36-44, respectively.

GROUPS XII-XX ARE LINKED BY CLAIMS 5, 8, AND 9

Groups XXI-XXX, claim 10 (in part), drawn to a process for the production of flour from transgenic seeds expressing a transglutaminase and a wheat storage protein comprising SEQ ID NO:11; wherein the wheat storage protein is not modified by mutagenesis for Group XXI; and wherein the wheat storage protein is modified by mutagenesis to eliminate allergenic amino acid sequence for food allergies to gluten and the sequence to be modified is specified for groups XXII-XXX; and wherein the sequence to be modified for groups XXII-XXX is SEQ ID NO: 36-44, respectively.

Groups XXXI-XL, claim 11 (in part), drawn to a process for producing a baked product that utilizes flour from transgenic seeds expressing a transglutaminase and a wheat storage protein comprising SEQ ID NO:11; wherein the wheat storage protein is not modified by mutagenesis for Group XXXI; and wherein the wheat storage protein is modified by mutagenesis to eliminate allergenic amino acid sequence for food allergies to gluten and the sequence to be modified is specified for groups XXXII-XL; and wherein the sequence to be modified for groups XXXII-XL is SEQ ID NO: 36-44, respectively.

Groups XLI-L, claim 12 (in part), drawn to a baked product that comprises flour from transgenic seeds expressing a transglutaminase and a wheat storage protein comprising SEQ ID NO:11; wherein the wheat storage protein is not modified by mutagenesis for Group XLI; and wherein the wheat storage protein is modified by mutagenesis to eliminate allergenic amino acid sequence for food allergies to gluten and the sequence to be modified is specified for groups XLII-L; and wherein the sequence to be modified for groups XLII-L is SEQ ID NO: 36-44, respectively.=

2. The inventions listed as Groups I-L do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-L is non-wheat plants, non-wheat seeds, or non-wheat flour comprising transglutaminase and a wheat storage protein comprising SEQ ID NO:11. Anderson, O.D. (WO 98/08607) teaches a high molecular weight (HMW) glutenin from wheat that comprises SEQ ID NO:11 (see sequence alignment and entire document). He teaches that HMW glutenin is important for flour quality, especially the viscoelasticity of the flour (see page 2). He teaches transgenic plants expressing engineered HMW glutenin (see Examples). Schuhmann, F. (US Patent No. 6,517,874, issued on Feb. 11, 2003; and filed as application No. 09/954,158 on Sept. 18, 2001) teaches that transglutaminase can be

added to flour blends comprising as little as 1% wheat flour to produce a baking flour mixture with favorable dough properties (see columns 1 and 2). It would have been obvious to combine the teachings of Anderson and Shuhmann to arrive at a transgenic non-wheat plant expressing HMW glutenin and transglutaminase; and this would not involve an inventive step. Therefore, the technical feature linking the inventions of groups I-L does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Accordingly, Groups I-L are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. Claims 1 and 4 link the inventions of groups I-X. Claims 5, 8, and 9 link the inventions of groups XI-XX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant applications. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is

advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cathy K. Worley/
Patent Examiner, Art Unit 1638